K080119

510(k) Submission
ESI, Inc
ClearScan Transducer Cover

510(k) Summary
November 16, 2007

FEB 21

(1) Submitter Information

Name: ESI, Inc.

Address: 2915 Everest Lane N.
Plymouth, MN 55447

Telephone Number: (763)473-2533

Contact Person: Dr. George Myers
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: November 16, 2007

(2) Name of Device:
Trade Name: ClearScan
Common Name: Cover for Ultrasonic Transducer
Classification Name: Ultrasonic Diagnostic Transducer Accessories, 90 ITX

(3) Equivalent legally-marketed devices:

K970573 Civco Poly Ultrasound Transducer Cover

K992152 Civco Ultrasound Transducer Standoff

(4) Description

The ClearScan™ ultrasound probe cover is intended to be used as a sterile, single-use protective cover with fluid coupling between the examined surface and an ultrasonic transducer. The device provides a microbial barrier between the probe and the patient's tissue, helping to prevent the transfer of microorganisms, body fluids and particulate material to the patient and healthcare personnel. It provides a water path between the transducer and the surface scanned.

The ClearScan™ material that contacts the eye or skin tissue is made of a soft pliable plastic film. The ClearScan is a sealable plastic sac that encloses the transducer and holds water to make the water path for scanning.

(5) Intended Use

The ClearScan™ ultrasound probe cover is intended to be used as a sterile, single-use protective cover with fluid coupling between the eye or skin and an ultrasonic transducer.

(6) Technological characteristics

The ClearScan is made of a biologically-compatible, non-latex membrane. It has a special collar that permits it to be sealed around the body of the transducer.

(7) Performance data

(a) Non-clinical tests

Biocompatibility tests have been done. Tests have been done to evaluate any possible distortion caused by the sac.

(b) Clinical tests

Not required

(8) Conclusions

The ESI ClearScan is equivalent in safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 21 2008

ESI, Incorporated
% Mr. George Myers
President
Medsys, Incorporated
377 Route 17 S
HASBROUCK HEIGHTS NJ 07604

Re: K080119
Trade/Device Name: ClearScan™ Transducer Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: January 14, 2008
Received: January 17, 2008

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080119

Device Name: ClearScan

Indications For Use:

The ClearScan™ ultrasound probe cover is indicated when it is necessary to have a sterile, single-use protective sheath with fluid coupling between the examined surface and an ultrasonic transducer.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080119